Reimbursement Steering Committee
Highlights of 2006 Final Rule for the Physician Fee Schedule

Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2006; Final Rule [Federal Register/ Vol. 70 No. 223/ Monday, November 21, 2005 / pp. 70116-70476]

Refer to the full text of the Final Rule for more information.

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I. Background (pp. 70118-70121)

A. Introduction (pp. 70118-70119)

The Social Security Act requires that payments under the physician fee schedule (PFS) be based on national uniform relative value units (RVUs) based on the resources used in furnishing a service. The Act requires that national RVUs be established for physician work, practice expense (PE), and malpractice expense.

Prior to the 1992 establishment of the resource-based relative value system, Medicare payment for physicians' services was based on reasonable charges.

The Act requires that RVU adjustments may not cause total physician fee schedule payments to change by more than $20 million.

B. Development of the Relative Value System (pp. 70119-70120)

This section describes the history of the implementation of resource based RVUs. The Act requires that CMS review all RVUs no less often than every five years.

The following table summarizes the historical changes to the Relative Value System.

Year	CMS Action
1992	Resource-based physician work RVUs established. Practice expense and malpractice RVUs based on average allowable charges.
1997	First 5-year review of physician work RVUs
1998	Implementation of resource-based practice expense RVUs delayed.
1999	First year of four-year transition to resource-based practice expense RVUs.
2000	Resource-based malpractice RVUs implemented based on malpractice premium data.
2002	Resource-based practice expense RVUs fully implemented. Site of service PE payment differential established. Second 5-year review of physician work RVUs.
2004	Through March of 2004, the AMA's RUC/PEAC (Practice Expense Advisory Committee) provided recommendations to CMS for over 7600 codes for the purpose of refining the direct PE inputs.
2005	First 5-year review of malpractice RVUs.
2007	Next scheduled 5-year review of physician work RVUs.

C. Components of the Fee Schedule Payment Amounts (p. 70120)

The general formula for calculating the Medicare fee schedule amount for a given service and fee schedule area can be expressed as:

Payment = [(RVU work x GPCI work) + (RVU PE x GPCI PE) + (RVU malpractice x GPCI malpractice)] x CF.

D. Most Recent Changes to the Fee Schedule (pp. 70120-70121)

This section summarizes changes from the CY 2005 Final Rule.

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II. Provisions of the Final Rule (pp. 70121-70273)

A. Resource-Based Work and Practice Expense Relative Value Units (RVUs) (pp. 70121-70150)

In response to the proposed rule, CMS received 15,000 comments. Comments came from physicians, professional associations, societies, beneficiaries, and health care workers.

1. Current Methodology

This section provides a history of how the Relative Value Units started and how it changed physician payment from historical allowed charges to the RVUs that are defined today. As of March 2004, the AMA's RUC, which established the Practice Expense Advisory Committee (PEAC) has provided recommendations for over 7600 codes. Now the PEAC has been replaced by the Practice Expense Review Committee (PERC) which assists the RUC in recommending PE inputs.

The current approach to the PE RVUs is referred to as "top down." The “top down” approach allocates aggregate specialty practice costs to specific procedures.

2 Practice Expense Proposals for 2006

In the proposed rule, CMS proposed to calculate PEs using the "bottom up" methodology rather than a “top down” methodology. The goals for the revision to the PE methodology were to ensure the PE payments reflect the actual relative resources required for each service, to develop a payment system that is understandable and intuitive, and to stabilize PE payments.

Due to an error in the CMS indirect PE calculation program, almost all of the PE RVUs published in the proposed rule were incorrect. CMS believes that as a result of this error interested parties were not given notice of the actual effect of the proposed changes in the PE RVU methodology and were not given sufficient opportunity to submit meaningful comments on the proposal.

After a multitude of comments, CMS withdrew its PE methodology proposal. CMS will maintain the current 2005 PE RVUs for CY 2006 with the following exceptions:

1. CMS will value the work and PE on an interim basis for all codes that are new in 2006.
2. As required by section 1848(c)(2)(I) of the Act, CMS will apply the PE/HR data from the urology supplementary survey to the calculation of the PE RVUs for all the drug administration codes performed by urology.
3. CMS will apply the savings from the implementation of the multiple procedure payment reduction for certain imaging services across all the PE RVUs that are discussed later in the preamble of this rule.

CMS will not use the accepted supplementary data in their indirect PE calculations for 2006 (with the exception of the urology PE/HR data that they are applying to the drug administration codes performed by urology). CMS is not using the other accepted supplementary PE data because, as explained above, they are not adopting the proposed changes to their PE methodology. CMS did not propose to use the survey data for calculating the direct PE RVUs and the use of the survey data would have caused significant changes in the PE RVUs for which there would have been no opportunity for comment.

There were many additional comments and concerns form a multitude of societies and specialties. CMS is continuing to review the PE methodology.

CMS believes that they should have data available to review the PE RVUs for drug administration services in time for a 2006 proposed rule.

3. PE Recommendations on CPEP Inputs for CY 2006

CMS adopted almost all of the PE recommendations from the RUC. CMS disagreed with the RUC recommendations for CPT 36522 and did not adopt the RUC recommendations for this code.

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The RUC recommended that no PE inputs be assigned to 15852, 76975, 78350, and 86585 because these services are not performed in the office setting; however, CMS proposed to have PE inputs for these codes because CMS data show that these codes are performed in the office setting. CMS will retain the nonfacility PE RVUs for 15852 and 76975 for 2006, but will remove them in the future. Based on comments, CMS will maintain the nonfacility PE RVUs for 78350 and work with the commenting specialty society to refine them in the future. CPT 86585 was deleted in 2006.

4. Payment for Splint and Cast Supplies

In 2000, CMS removed cast and splint supplies from the PE database for the CPT codes for fracture management and cast/strapping application procedures because casting supplies could be billed separately with HCPCS codes. In doing so, CMS unintentionally prohibited payment when these supplies are furnished incident to a physician's service.

CMS proposed to eliminate the HCPCS "Q" codes for casting supplies and incorporate the costs into the practice expense of the CPT codes. Because the supplies were removed from the PE database prior to refinement, CMS requested feedback on the practice expense inputs and type and amount of casting supplies needed for 10 and 90 day global procedures.

Based on comments, CMS will work with affected specialties and the RUC regarding this proposal. CMS will continue to use the HCPCS "Q" codes for casting materials for 2006.

5. PE Recommendations on CPEP Inputs for CY 2006

CMS is making limited changes to the PE RVUs for 2006. Although the PE database is being updated, most PE changes will not take place in 2006.

Supply Items for CPT Code 95015
CMS updated their PE database for 95015 based on JCAAI comments. The database changes do not affect the 2006 PFS.

Flow Cytometry Services
CMS updated their PE database for flow cytometry codes 88184 and 88185 based on specialty society comments. The database changes do not affect the 2006 PFS.

Low Osmolar Contrast Media (LOCM) and High Osmolar Contrast Media (HOCM)
CMS proposed to no longer pay for HOCM under the PFS but to establish "Q" codes for separate payment. Because CMS is not implementing the "bottom-up" methodology, CMS is also delaying separate payment for HOCM.

Imaging Rooms
CMS included standardized "rooms" for certain service in the PE equipment database instead of listing each item separately. When supplies are over a $500 threshold, CMS will include the costs specific to the room. CMS adopted changes for the PE inputs for certain radiology rooms based on input. The database changes do not affect the 2006 PFS.

Equipment Pricing for Select Services and Procedures from the CY 2005 Final Rule
CMS requested feedback on equipment pricing for some radiology and other services. CMS did not receive any comments so is implementing the proposed prices. The database changes do not affect the 2006 PFS.

Supply Items for In Situ Hybridization Codes (CPT 88365, 88367, and 88368)
CMS accepted the College of American Pathologists' request to assign 1.5 probes to CPT code 88367 (which is the same number of probes assigned to other in situ hybridization codes). The PE database changes do not affect the 2006 PFS.

Supply Items for Percutaneous Vertebroplasty Procedures (CPT Codes 22520 and 22525)
CMS accepted the Society for Interventional Radiology pricing of the vertebroplasty kit used in CPT 22520 and 22525. The PE database changes do not affect the 2006 PFS.

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Clinical Labor for G-Codes Related to Home Health and Hospice Physician Supervision, Certification and Recertification
In 2004, CMS refined the inputs for CPT 99375 and 99378. The inputs for G0179-G0182 should have also been refined at the same time, but were not; CMS is correcting this oversight and is changing the PE inputs for these codes. The PE database changes do not affect the 2006 PFS.

Programmers for Implantable Neurostimulators and Intrathecal Drug Infusion Pumps
CMS had proposed to remove the cost of programmers for implantable neurostimulators and intrathecal drug infusion pumps from the PE database based on information from a manufacturer that these items are provided for free. However, based on further information that these items are generally not provided free of charge, CMS is retaining the cost of these programmers in the PE database.

Pricing of New Supply and Equipment Items
CMS is changing the laboratory equipment identifier in the PE database to EPXXX, it had been assigned the same identifier as the "lanes/rooms" category.

Supply and Equipment Items Needing Specialty Input
CMS requested input on pricing information for certain supply and equipment items. The supply items and input received are in tables 14 and 15 (pp. 70142-70147).

Additional PE Issues Raised by Commenters
There were a number of comments requesting changes to PE RVUs. For the most part, CMS either disagreed with the comments, or instructed the commenters to take their requests to the RUC through their specialty societies. CMS will adopt some changes suggested by commenters, but the changes will not affect the 2006 PFS.

In response to comments CMS has:
- corrected some errors for codes that had "NA" for the nonfacilty RVUs;
- added a tilt table to the equipment for 36475-36476;
- added requested equipment on an interim basis for 77332-77333;
- added labor time to the nonfacility RVUs for G0166;
- changed the equipment time for 93701;

Additionally, CMS will be working with provider organizations about their concerns of inappropriate PE RVUs for cardiac event monitoring with the "bottom up" PE method.
Based on the RUC comment that high cost medical equipment needs to be reviewed more than every 5 years, CMS is considered options for revaluing these items and will include a discussion of this issue in the next proposed rule.

At the request of the RUC, CMS has been working directly with representatives of maxillofacial prosthetics to refine PE inputs for CPT codes 21076-21087. CMS is continuing to work will the specialty to refine these inputs before the next proposed rule.

B. Geographic Practice Cost Indices (GPCIs) (pp. 70150-70153)

CMS is required to develop separate GPCIs to measure resource cost differences among localities compared to the national average for each of the three fee schedule components. The practice expense and malpractice GPCIs must reflect the full relative cost differences, but the physician work GPCIs must reflect only one quarter of the relative cost differences compared to the national average.

The MMA established a 1.0 work GPCI floor for any locality where the GPCI would otherwise fall below 1.0 for dates of service after January 1, 2004 and before January 1, 2007. The 1.0 work GPCI floor will remain in effect for CY 2006.

Effective January 1, 2006, the provision for a 1.67 floor for Alaska's work, practice expense and malpractice GPCIs will end. The 2006 GPCIs for Alaska will be: 1.017 (work), 1.103 (practice expense), and 1.029 (malpractice).

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CMS proposed to change the 2006 GPCIs and GAFs for Santa Cruz County, Sonoma County and the Rest of California effective January 1, 2006 and asked for comments regarding this proposal, particularly from the California Medical Association. Because of the nearly complete lack of support for this proposal outside the two positively impacted counties, CMS withdrew the proposal for CY 2006. CMS will work with MedPAC and other interested parties toward a more comprehensive evaluation of potential refinements of the payment localities.

The 2006 GPCIs by Medicare Carrier and Locality are listed in Addendum D and the 2006 GAFs are listed in Addendum E. The GPCIs and GAFs for Washington State are in the table below:

Carrier	Locality	Locality Name	2006 Work GPCI	2006 PE GPCI	2006 MP GPCI	2006 GAF
00836	02	Seattle (King Cnty), WA	1.014	1.131	0.819	1.058
00836	99	Rest of Washington	1.000	0.978	0.819	0.984

C. Malpractice Work RVUs (pp. 70153-70155)

1. Five Percent Specialty Threshold

As proposed, CMS has implemented a 5 percent specialty threshold for the calculation of malpractice RVUs. This threshold excludes data for any specialty that performs less than 5 percent of a particular service or procedure from the malpractice RVU calculation. The majority of commenters supported this proposed change.

2. Specialty Crosswalk Issues

CMS is adopting the risk factor changes presented in the proposed rule.

CMS is assigning a **risk factor of 1.0** to the following specialties: clinical psychology; licensed clinical social work; psychology; occupational therapy: opticians and optometrists; chiropractic, and physical therapy.

CMS is **excluding the following professions** that were assigned to the average for all physicians risk factor from the data used in the calculation of malpractice RVUs: certified clinical nurse specialist; clinical laboratory; multispecialty clinic or group practice; nurse practitioner; physician assistant; and physiological laboratory (independent).

CMS is not accepting the PLI workgroup recommendations to change the risk group crosswalks for the following specialties: CRNAs; colorectal surgeons; and gynecologists and oncologists.

3. Cardiac Catheterization and Angioplasty Exception

Since 2000, CMS has applied surgical risk factors to the following cardiology catheterization and angioplasty codes because they are invasive and closer to surgical than non-surgical codes: 92980-92998 and 93501-93536. As proposed, CMS has added the following codes to the existing list of exception codes in 2006: 92975, 92980-92998, and 93617-93641. Commenters supported this change.

4. Dominant Specialty for Low-Volume Codes

The RUC-PLI workgroup recommended using a dominant-specialty approach for low-volume codes. CMS is not adopting the RUC recommendation. Numerous commenters opposed the CMS policy to use actual specialty data and suggested that CMS adopt the RUC recommendation.

5. Collection of Premium Data

Some commenters suggested that CMS use data supplied by the Physicians Insurers Association of America (PIAA) or providers' self-reported premium costs as CMS's source for premium data. CMS is

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evaluating the usefulness of the PIAA data before making a decision. CMS is not considering using provider's self-reported costs.

D. Medicare Telehealth Services (pp. 70155-70160)

CMS has two categories for reviewing requested changes to the approved telehealth services. For services falling in the second category, requestors should submit evidence showing that the use of a telecommunications system does not affect the diagnosis or treatment plan as compared to a face-to-face delivery of the service.

Category 1—Services that are similar to office and other outpatient services, which may be similar to telehealth services already allowed; and

Category 2—Services that are not similar to the current list of allowed telehealth services

Requested Telehealth Additions:

CMS received requests for the following changes to telehealth approved services:

- Individual medical nutritional therapy (MNT) (HCPCS codes G0270, 97802 and 97803);
- Group MNT (HCPCS codes G0271 and 97804);
- Individual diabetes outpatient self-management training (DSMT) services (HCPCS code G0108);
- Group DSMT(HCPCS code G0109);
- Modification of the definition of an interactive telecommunications system for purposes of furnishing a telehealth service.

Services Added to the Telehealth List in 2006

CMS has added the following services to the list of approved telehealth services:

- Individual medical nutritional therapy (MNT) (HCPCS codes G0270, 97802 and 97803);
- Group MNT (HCPCS codes G0271 and 97804);

CMS has added registered dietitians and nutrition professionals to the list of practitioners who may furnish and receive payment for telehealth services.

CMS does not have the authority to change the definition of an interactive telecommunications system for because this is a legislative mandated service.

E. Contractor Pricing of Unlisted Therapy Modalities and Procedures (pp. 70160-70161)

CMS removed the RVUs for unlisted procedure codes 97039 and 97139. These codes are now contractor priced and have been assigned a status indicator of "C."

F. Payment for Teaching Anesthesiologists (p. 70161)

CMS did not find any comments to cause them to change the current Teaching Anesthesiologists policy. CMS will continue to review the information and relevant data presented by the commenters and consult with stakeholders before moving forward with any proposal.

G. End Stage Renal Disease (ESRD) Related Provisions (pp. 70161-70215)

CMS updated the add-on adjustment to reflect estimated growth in ESRD drug expenditures of 0.7 percent. CMS combined the add-on adjustment of 8.1 percent that reflects the payment methodology CMS will be using for ESRD drugs with the 0.7 percent increase for expenditures in 2006 to produce one proposed drug add-on adjustment for CY 2006 of 8.9 percent.

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H Payment for Outpatient Drugs and Biologicals (pp. 70215-70260)

1. ASP Issues

In the first part of this section, CMS explains briefly its drug coverage and payment using the Average Sales Price (ASP) methodology.

a. Estimation methodology

CMS describes the current methodology for determining ASP which uses an average of direct and indirect sales to arrive at the price. CMS proposed to modify the methodology to reduce the variation in pricing resulting from changing ratios of direct and indirect sales. All but one comment opposed the modification stating the administrative burden would be high and the difference in price would not be that great. Price estimates given ranged from a reduction of 1 percent to an increase of 4 percent.

b. Price concessions: Wholesaler chargebacks

CMS decided not to adopt the proposed changes in ASP pricing but is interested in working on methods to improve the accuracy of the pricing and to ensure access.

c. Determining the payment amount based on ASP data

CMS describes its methodology for converting manufacturers' ASP per NDC into the billing units used by CMS. In response to comments, CMS stated it would consider altering the methodology if it finds good reason to do so. Comments were made about the availability of IVIG and the inability to obtain it for ASP + 6 percent. CMS responded by establishing a new code, G0332, to account for preadministration services related to IVIG infusion.

d. Reporting WAC

Manufacturers must report the Wholesale Acquisition Cost (WAC) for all single source drugs each reporting period. Manufacturers must submit the WAC that is in effect on the last day of the reporting period.

e. Revised format for submitting ASP

- Drug name
- Package size
- Expiration date for last lot manufactured
- Date the NDC was first marketed (effective 10/1/05)
- Date of first sale for products first sold on or after 10/1/05

All timely comments were not received and considered before the rule was finalized. Changes to the ASP collection information will be finalized at a later date.

f. Limitations on ASP

CMS may ignore the ASP if the drug's widely available market price or average manufacturer's price is more than 5% lower than ASP. CMS will maintain 5% as the threshold for CY 2006.

2. Payment for drugs furnished during CY 2006 in connection with the furnishing of renal dialysis services if separately billed by renal dialysis facilities

CMS will pay ASP + 6 percent to all free standing ESRD facilities for drugs separately billed by these facilities. In CY 2005, CMS paid for these drugs using acquisition costs.

3. Clotting factor furnishing fee

The furnishing fee for clotting factors, currently $0.14, for years after CY 2005 must be increased by the increase in the medical CPI for the year ending the previous June. The CPI for the year ending June 2005 was not available for the proposed rule, but is now available. The percent increase was 4.2 percent so the furnishing fee will be $0.146 for 2006. Actual payments will be rounded to two digits.

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4. Payment for inhalation drugs and dispensing fee

CMS decided to maintain the initial month's dispensing fee at $57 and each additional month at $33. The dispensing fee for a 90 day supply will remain at $80.

5. Supplying fee

CMS is proposing to change the supplying fee for covered oral immunosuppressive, chemotherapeutic and anti-emetic drugs to $24 for the first prescription (except for a $50 fee for an initial immunosuppressive drug post transplant) and $8 for each additional drug supplied during a month. Currently, CMS is paying $24 for each covered prescription supplied. CMS is also proposing to pay a separate supplying fee for each prescription filled on the same day for different strengths of the same drug. Currently, CMS only pays one supplying fee per drug dispensed regardless if there are multiple prescriptions or strengths. CMS decided to pay a supplying fee of $24 for the first prescription in a 30 day period and $16 for each additional prescription including different strengths of the same drug. CMS will continue to pay $50 for an initial immunosuppressive drug post transplant.

6. Competitive Acquisition of Outpatient Drugs and Biologicals Under Part B

Physicians who administer drugs in their offices to Medicare beneficiaries will have the option of obtaining many of these drugs under a new voluntary competitive acquisition program (CAP) starting on July 1, 2006.

The Competitive Acquisition Program (CAP) will provide physicians with two choices for procuring drugs and biologicals for their patients.

- Obtain drugs from entities selected to participate in the CAP.
- Acquire and bill for covered drugs under the ASP payment methodology.

If the physician chooses to obtain the drugs from a CAP entity, Medicare will match the claims from the physician and the entity. The basic process is described below.

- Beneficiary visits office, physician orders drug. Specifies a window for drug administration.
- Drug order is received by the CAP entity and is shipped to the physician. The entity submits the claim to Medicare at the beginning of the specified window. A 14-day "payment floor" clock starts.
- The physician receives the drug and administers it within the specified window. Physician then has 14 days to submit the claim. The physician's "payment floor" begins when the claim is filed.
- Medicare matches the two claims and pays the drug claim after the "payment floor" timeframe is met.
- Medicare pays the physician's claim after the "payment floor" timeframe is met.

I. Private Contracts and Opt-out Provision (pp. 70260-70261)

CMS amended Sec.405.435 to clarify that the consequences for the failure on the part of a physician or practitioner to maintain opt-out will apply regardless of whether or when a carrier notifies a physician or practitioner of the failure to maintain opt-out. CMS also added a new paragraph to clarify that in situations where a violation is not discovered by the carrier during the 2-year opt-out period when the violation actually occurred, then the requirements would be applicable from the date that the first violation occurred until the end of the opt-out period during which the violation occurred (unless the physician or practitioner takes good faith efforts to restore opt-out conditions, for example, by refunding the amounts in excess of the charge limits to beneficiaries with whom he or she did not sign a private contract). These good faith efforts must be made within 45 days of any notice by the carrier that the physician or practitioner has failed to maintain opt-out (where the carrier discovers the failure after the 2-year opt-out period has expired), or within 45 days after the physician or practitioner has discovered the failure to maintain opt-out, whichever is earlier.

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J. Multiple Procedure Reduction for Diagnostic Imaging (pp. 70261-70265)

In 1995 Medicare began applying multiple procedure reductions to the following nuclear medicine diagnostic procedure codes: 78306, 78320, 78802, 78803, 78806, and 78807. Although not mentioned in the Proposed or Final Rule, it appears Medicare discontinued the multiple procedure reduction for 78306 and 78320 in 2003 (based on the multiple surgery indicators for these codes).

CMS proposed a multiple procedure reduction for radiology services in 11 radiology families. The radiology families are defined by imaging modality and contiguous body area. The payment reduction would apply to the technical component of the procedure only. The payment reduction would apply to services within the same radiology family and not when services from separate families are provided in the same session. CMS proposed the reduction because they believe that duplicate payment was being made for the technical component of multiple diagnostic imaging services, particularly when contiguous body parts are viewed in a single session.

CMS adopted the multiple procedure reduction for radiology services, with the following revisions based on comments on the proposed rule. The changes compared to the proposed rule are:

- CMS deleted transvaginal ultrasound (CPT 76830) and ultrasound of the breast (CPT 76645) from the list of procedures subject to the multiple procedure reduction, this decision is pending further study.
- CMS will phase in the multiple procedure over a 2 year period, with a 25 percent reduction for multiple procedures in CY 2006 and a 50 percent reduction in CY 2007.

The radiology families and associated procedure codes are outlined in the table below:

Radiology Family	Imaging Modality	Body Area	Codes in Family
Family 1	Ultrasound	Chest / Abdomen / Pelvis-Non-Obstetrical	76604, 76700, 76705, 76770, 76775, 76778, 76831, 76856, 76857
Family 2	CT and CTA	Chest / Thorax / Abd / Pelvis	71250, 71260, 71270, 71275, 72191, 72192, 72193, 72194, 74150, 74160, 74170, 74175, 75635, 0067T
Family 3	CT and CTA	Head / Brain / Orbit / Maxillofacial / Neck	70450, 70460, 70470, 70480, 70481, 70482, 70486, 70487, 70488, 70490, 70491, 70492, 70496, 70498
Family 4	MRI and MRA	Chest / Abd / Pelvis	71550, 71551, 71552, 71555, 72195, 72196, 72197, 72198, 74181, 74182, 74183, 74185
Family 5	MRI and MRA	Head/Brain/Neck	70540, 70542, 70543, 70544, 70545, 70546, 70547, 70548, 70549, 70551, 70552, 70553
Family 6	MRI and MRA	Spine	72141, 72142, 72146, 72147, 72148, 72149, 72156, 72157, 72158
Family 7	CT	Spine	72125, 72126, 72127, 72128, 72129, 72130, 72131, 72132, 72133
Family 8	MRI and MRA	Lower extremities	73718, 73719, 73720, 73721, 73722, 73723, 73725
Family 9	CT and CTA	Lower extremities	73700, 73701, 73702, 73706
Family 10	Mr and MRI	Upper extremities and joints	73218, 73219, 73220, 73221, 73222, 73223
Family 11	CT and CTA	Upper extremities	73200, 73201, 73202, 73206

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K. Therapy Cap (p. 70266)

The per beneficiary caps on outpatient physical therapy, occupational therapy, and speech-language pathology services have been reinstated effective January 1, 2006. The dollar amount for the therapy caps for CY 2006 is $1,740.

L. Chiropractic Demonstration Discussion (pp. 70266-70267)

Medicare covers three CPT codes for chiropractic services: 98940, 98941, 98942. Treatment must be provided for an active subluxation only, and not for prevention or maintenance. Additionally, treatment of the subluxation must be related to a neuromusculoskeletal condition where there is a reasonable expectation of recovery or functional improvement.

Medicare is conducting a 2-year demonstration project to evaluate the feasibility and advisability of covering additional chiropractic services.

PT services performed by chiropractors under the demonstration will be included under the PT cap described in section II.K. These services are included under the cap because chiropractors are subject to the same rules as medical doctors for therapy services under the demonstration.

The demonstration will be budget neutral. Any needed fee schedule reductions would occur in 2010 and 2011. Because the demonstration is located in only four sites in which the expansion of services is permitted, CMS anticipates that the impact on the SGR would be negligible.

M. Supplemental Payments to Federally Qualified Health Centers (FQHCs) Subcontracting with Medicare Advantage Plans (pp. 70267-70270)

A supplemental payment will be made every time a face-to-face encounter occurs between an MA enrollee and any one of the FQHC's core practitioners: physician, nurse practitioner, physician assistant, clinical nurse midwife, clinical psychologist, or clinical social worker. The supplemental payment is made directly to each FQHC through the Medicare Fiscal Intermediary (FI).

CMS revised Sec. 405.2469 as proposed with one change, the first use of the term “Medicare Advantage plans” is revised to read “Medicare Advantage organizations.'”

Some highlights from this section:

- FQHC must accept the MA payment and the Federal supplemental payment as payment in full for services covered by the agreement, except the FQHC may collect any amount of cost-sharing permitted under the MA contract, so lonas as the amounts of any deductible, coinsurance, or co-payment comply with the requirements under sections 1854(e) of the Act.
- Rules regarding what may constitute “bad debt” for purposes of a FQHC’s cost report are byond the scope of final rule.
- The FQHC should bill original Medicare only for covered services rendered to original Medicare beneficiaries that are not enrolled in an MA plan.
- CMS crossover processes to not apply to MA claims but rather to claims that are processed under original Medicare, fee-for-service contractor operations.

N. National Coverage Decisions Timeframes (p. 70270)

CMS will finalize the changes to Sec 426.340 as proposed with minor technical edits, and will continue to work diligently to assure that all NCDs submitted after the December 8, 2003 effective date for the statutory change are developed within the set timeframes.

O. Coverage of Screening for Glaucoma (pp. 70270-70272)

CMS is revising the definition of an eligible beneficiary who is at `high risk'' for glaucoma to include Hispanic-Americans age 65 and older as proposed.

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P. Additional Issues (pp. 70272-70273)

1. Corrections to Conditions for Medicare Payment

CMS corrected two typographical errors, one referencing the wrong subsection for the definition of "financial relationship," and the other correcting a spelling error in a footnote.

2. Chemotherapy Demonstration Project

CMS has reconfigured their chemotherapy demonstration project for 2006. The ongoing Oncology Demonstration Project will:

- Build on the use of G codes to gather more specific information relevant to the quality of care for cancer patients, their treatments, and the spectrum of care they receive from their doctors, and whether or not the care follows clinical guidelines.
- Emphasize evidence-based practice guidelines that have been shown to lead to better patient outcomes as the source for standard of care, permitting us to monitor and encourage quality care to cancer patients.
- No longer be specific to chemotherapy administration services, but instead will be associated with physician E/M visits for established patients with cancer, visits that are frequent and essential to assuring quality of care and life for patients.

The demonstration project is available to office-based hematologists/oncologists who provide an E/M service of level 2-5 to an established patient when the primary diagnosis belongs to one of the following categories:

- Breast cancer (invasive)
- Colon cancer
- Rectal cancer.
- Prostate cancer.
- Lung cancer (either non-small cell or small cell).
- Stomach cancer.
- Esophageal cancer.
- Pancreatic cancer.
- Ovarian cancer.
- Non-Hodgkins Lymphoma.
- Chronic myelogenous leukemia.
- Multiple myeloma.
- Cancer of the head and neck.

Physicians may receive a $23 payment from Medicare when they report one G-code from each of the following categories when an E/M service of level 2-5 is billed:

1. The primary focus of the E/M service
2. The current disease status
3. Whether current management adheres to clinical guidelines

III. Refinement of RVUs for CY 2006 and Response to Public Comments on Interim RVUs for 2005 (pp. 70273-70283)

A. Summary of Issues Discussed Related to the Adjustment of Relative Value Units (p. 70273)

Section III.B and III.C of this final rule with comment describes the methodology used to review the comments received on the RVUs for physician work and the process used to establish RVUs for new

and revised CPT codes. Changes to codes on the PFS reflected in Addendum B are effective for services furnished beginning January 1, 2006.

B. Process for Establishing Work Relative Value Units for the 2005 Physician Fee Schedule (pp. 70273)

CMS considers the work RVUs for new and revised codes published in the final rule to be interim and subject to public comment under the annual refinement process. Section III summarizes the refinements to the interim work RVUs published in the CY 2005 final rule and the establishment of the work RVUs for new and revised codes for the 2006 PFS.

C. Work Relative Value Unit Refinements of Interim Relative Value Units (pp. 70273-70275)

CMS received substantive comments on 7 codes with interim work RVUs in 2005. Comments for two of the codes were reviewed by a multispecialty panel of physicians; representatives from the organizations sending comments were invited to attend the panel meeting. The refinement panel compared the work for the code being reviewed to the work for 75 reference services.

Two codes were reviewed under the refinement panel process, 97605 and 97606. The review resulted in the codes changing from bundled to having RVUs (see Table 28, p. 70274).

D. Establishment of Interim Work Relative Value Units for New and Revised CPT Codes and New HCPCS for 2006 (pp. 70275-70281)

CMS received work RVU recommendations from the RUC for 175 new and revised CPT codes; CMS accepted approximately 94 percent of the RUC recommended values.

CMS received 9 recommendations from the Health Care Professional Advisory Committee (HCPAC); CMS agreed with seven of the HCPAC recommendations.

Table 29 (pp. 70277-70280) includes the RUC and HCPAC work RVU recommendations, CMS's decision, and the interim RVUs for 2006.

Table 30 (p. 70281) includes the RUC anesthesia base unit recommendations for new codes and CMS's decision.

E. Discussion of Codes for Which There Were No RUC Recommendations or for Which the RUC Recommendations Were Not Accepted (pp. 70281-70282)

This section includes CMS's rationale for not accepting the RUC recommendations.

F. Establishment of Interim PE RVUs for New and Revised CPT and New HCPCS Codes for 2006 (pp. 70282-70283)

This section describes how interim practice expense RVUs were established for CPT 28890 and 89049.

IV. Five-Year Refinement of RVUs – Status Update (p. 70283)

CMS solicited comments on potentially inappropriately valued RVUs in the CY 2005 final rule. Because comments tend to focus on undervalued services, CMS identified additional services to review by finding services that were not previously reviewed by the RUC and that are valued as being performed in an inpatient setting but are now predominantly outpatient services.

CMS will consider all comments and propose work RVU revisions in a proposed rule in 2006. CMS will review comments from the proposed rule and publish their decisions in the final rule for CY 2007.

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V. Physician Self-Referral Prohibition: Nuclear Medicine and Annual Update to the List of CPT/HCPCS Codes (pp. 70283-70298)

A. General (p. 70283)

Physicians are prohibited from referring Medicare beneficiaries for certain designated health services (DHS) to a health care entity with which they have a financial relationship (unless an exception applies).

The following services are considered designated health services (DHS):

- Clinical laboratory services.
- Physical therapy, occupational therapy, and speech-language pathology services.
- Radiology and certain other imaging services.
- Radiation therapy services and supplies.
- Durable medical equipment and supplies.
- Parenteral and enteral nutrients, equipment, and supplies.
- Prosthetics, orthotics, and prosthetic devices and supplies.
- Home health services.
- Outpatient prescription drugs.
- Inpatient and outpatient hospital services.

B. Nuclear Medicine (pp. 70283-70295)

CMS proposed to add diagnostic and therapeutic nuclear medicine procedures as designated health services (DHS). CMS has delayed the effective date of this regulatory change until January 1, 2007. CMS believes this delay provides adequate notice to the general public and a reasonable length of time for physicians to divest any existing ownership interests or to restructure their financial relationships with nuclear medicine entities so that they comply with a statutory or regulatory exception.

Table 31 (pp. 70290-70295) includes the list of nuclear medicine codes that will be subject to the physician self-referral prohibition effective January 1, 2007.

C. Annual Update to the Code List (pp. 70296-70298)

CMS annually updates the code list for designated health services in the following categories:

- Clinical laboratory services.
- Physical therapy, occupational therapy, and speech-language pathology services.
- Radiology and certain other imaging services.
- Radiation therapy services and supplies.

The code list is in addendum H of the final rule. Table 32 (p. 70297) includes a list of codes added to the list since 2005. Table 33 (p. 70298) includes a list of codes deleted from the list since 2005.

CMS is adding CPT 78267 and 78268 for urea breath tests and analyses to the DHS category of clinical laboratory services. Although these codes appear under the nuclear medicine subheading in the CPT, they do not represent imaging services. CMS is adding these codes to the Code List under the clinical laboratory services category. This is consistent with the payment policy, since these codes are reimbursed under the clinical laboratory fee schedule.

Additionally, CMS is adding CPT code 92506 for the evaluation of speech, language, voice, communication, and/or auditory processing. CMS deleted this code in the Phase II physician self-referral interim final rule published on March 26, 2004 (69 FR 16054) because it represented an audiology service. However, Medicare does not provide reimbursement for CPT code 92506 as an audiology service. Under Medicare, that code is only reimbursed as a speech-language pathology service and therefore must be added to the Code List.

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VI. Physician Fee Schedule Update for CY 2006 (pp. 70298-70304)

A. Physician Fee Schedule Update (pp. 70298-70299)

By statute, the PFS update is determined by multiplying the 1 plus the Medicare Economic Index (MEI) by 1 plus the update adjustment factor (UAF). For CY 2006, MEI is 2.8 percent and the UAF is -7.0 percent.

The calculation for the CY 2006 PFS update is:

- (MEI +1) x (UAF +1) = 1.028 x 0.930 = 0.9560
- Percent change = 1 minus 0.9560 = -0.044 = -4.4 percent

B. The Percentage Change in the Medicare Economic Index (MEI) (pp. 70299-70300)

This section describes how the Medicare Economic Index is calculated.

C. The Update Adjustment Factor (pp. 70301-70304)

This section describes how the Update Adjustment Factor is calculated.

VII. Allowed Expenditures for Physicians' Services and the Sustainable Growth Rate (pp. 70304-70312)

The SGR is an annual growth rate that applies to physicians' services paid by Medicare. The use of the SGR is intended to control growth in aggregate Medicare expenditures for physicians' services.

Section 1848(f)(2) of the Act specifies that the SGR for a year (beginning with 2001) is equal to the product of the following four factors:

A. The estimated change in fees for physicians' services;
B. The estimated change in the average number of Medicare fee-for-service beneficiaries;
C. The estimated projected growth in real gross domestic product (GDP) per capita; and
D. The estimated change in expenditures due to changes in statute or regulations.

Medicare has included a table and a multitude of comments regarding this issue.

VIII. Anesthesia and Physician Fee Schedule Conversion Factors for CY 2006 (pp. 70312-70313)

A. Physician Fee Schedule Conversion Factor (p. 70312)

2005 Conversion Factor $37.8975
2006 Update -4.4 percent
2006 Adjustment for Work RVU Changes .9985
2006 Conversion Factor $36.1770

B. Anesthesia Fee Schedule Conversion Factor (p. 70313)

2005 Anesthesia Conversion Factor $17.7594
2006 Update -4.4 percent
2006 Adjustment for Work RVU Changes .9985
2006 Adjustment for PE Changes 1.00039
2006 Anesthesia Conversion Factor $16.9591

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IX. Telehealth Originating Site Facility Fee Payment Amount Update (p. 70313)

Medicare's telehealth originating site fee was originally established at $20. The Act requires that Medicare increase the fee annually based on the Medicare Economic Index (MEI). For CY 2006, the MEI was 2.8 percent; therefore the payment amount for Q3014 (telehealth originating site facility fee) is 80 percent of the lesser of the actual charge or $22.47.

X. Provisions of the Final Rule with Comment (p. 70313)

See preamble.

XI. Waiver of Proposed Rulemaking (p. 70313)

CMS waives the proposed rulemaking process for adopting the new CPT and HCPCS codes and establishing RVUs for these codes. Because of the timing of the release of the new codes it is impractical for CMS to provide prior notice and solicit comment on these codes and RVUs. The new codes and interim RVUs are published in Addendum C. CMS is providing a 60-day public comment period for the interim RVUs.

XII. Collection of Information Requirements (pp. 70313-70314)

CMS is required to provide 60-day notice in the Federal Register and solicit public comment before a collection of information requirement is submitted to the Office of Management and Budget (OMB) for review and approval.

CMS is required to solicit comment on the need for the proposed information collection, the accuracy of CMS's estimate of the burden of the information collection requirement, the quality, utility and clarity of the information to be collected and any recommendations to minimize the information collection burden.

CMS continues to solicit public comment on the information collection requirements for pediatric ESRD facilities requesting an exception to payment rates and for manufacturers reporting ASP data to CMS.

XIII. Response to Comments (p. 70314)

CMS will consider all comments received by 5 PM January 3, 2006, and will respond to the comments in the preamble to a subsequent document.

XIV. Regulatory Impact Analysis (pp. 70314-70335)

CMS has determined that this final rule with comment would have minimal impact on small hospitals located in rural areas. CMS estimates that the combined impact of the changes to payment for renal dialysis services included in this final rule with comment would have a 1.5 percent decrease in payments relative to current payments. CMS stated that this regulation would not have any significant impact on the rights, roles, or responsibilities of State, local, or tribal governments.

A. Resource-Based Work and Practice Expense Relative Value Units (RVUs) (pp. 70315-70316)

For PE RVUs, CMS policy has been to meet the budget-neutrality requirements in the statute by incorporating a rescaling adjustment in the PE methodologies. That is, CMS estimates the aggregate number of PE RVUs that will be paid under current and revised policy in CY 2006.

B. Malpractice RVUs (p. 70316)

The impact of the methodological changes in the calculation of resource-based malpractice expense RVUs is negligible as malpractice RVUs account for less than 4 percent of total payments.

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C. Multiple Imaging Procedures (pp. 70316-70317)

As expected, the most significant impacts occur among radiologists, who would experience a -1 percent impact. Diagnostic testing facilities also experience a -1 percent impact.

Most other specialties experience a very small (0.1 percent) payment increase as a result of the budget neutrality adjustment. (Because this multiple procedure reduction adjustment would otherwise reduce overall payments by 0.1 percent, it is necessary to include a budget neutrality adjustment to the PE RVUs, resulting in positive impacts for most specialties.) Table 49 shows the percentage impact by specialty in combination with other changes being implemented.

D. Combined Impacts (pp. 70317-70323)

Multiple tables outline the combined impacts of Medicare's changes for 2006. The following are examples of discussion in this section:

The payment impacts reflect averages for each specialty based on Medicare utilization. The payment impact for an individual physician would be different from the average, based on the mix of services the physician provides. The average change in total revenues would be less than the impact displayed here because physicians furnish services to both Medicare and non-Medicare patients and specialties may receive substantial Medicare revenues for services that are not paid under the PFS.

Table 49 shows the specialty level impact on payment of the work RVU changes, practice expense RVU changes, malpractice RVU changes, and multiple imaging payment changes being implemented for CY 2006.

Table 50 shows the impact on total payments for selected high-volume procedures of all of the changes previously discussed. CMS selected these procedures because they are the most commonly provided by a broad spectrum of physician specialties. There are separate columns that show the change in the facility rates and the nonfacility rates. For an explanation of facility and nonfacility PE refer to section II.A in the preamble of this final rule with comment.

E. Medicare Telehealth Services (p. 70323)

CMS is adding individual medical nutrition therapy, as represented by HCPCS codes G0270, 97802, and 97803, to the list of telehealth services. CMS believes this change will have little effect on Medicare expenditures.

F. Contractor Pricing of CPT codes 97039 and 97139 (p. 70323)

As discussed earlier in the preamble of this final rule with comment (section II.E.), CMS will have the contractors value CPT codes 97039 and 97139.

G. ESRD-MMA Related Provisions (pp. 70323-70326)

The overall impact on ESRD providers in the aggregate is 1.2 percent increase. CMS provided a State-specific impact analysis in Table 53.

H. Payment for Covered Outpatient Drugs and Biologicals, and CAP Provisions (p. 70327)

The changes to the supplying fee for immunosuppressive, oral anticancer, and oral anti-emetic drugs are estimated to reduce total Federal expenditures by $2 million in 2006, and $14 million over the 5-year period, CY 2006 to 2010. The changes to the inhalation drug dispensing fee are expected to reduce total Federal expenditures by $120 million in 2006, and $720 million over the 5-year period, CY 2006 to 2010.

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I. Private Contracts and Opt-out Provision (p. 70327)

The changes discussed in section II.I of this final rule with comment, with respect to private contracts and the optout provision, are estimated to have no significant impact on Medicare expenditures.

J. FQHC Supplemental Payment Provisions (p. 70327)

No significant impact.

K. Coverage of Screening for Glaucoma (p. 70327)

No significant impact.

L. National Coverage Decision Timeframes (p. 70327)

There are no budget implications as a result of these changes.

M. Physician Referral for Nuclear Medicine Services (p. 70327-70328)

Although the impact on an individual physician may be significant, CMS does not believe that physicians, in general, will be significantly affected if they are required to stop making referrals to an entity in which they have an ownership interest.

N. Alternatives Considered (p. 70328)

CMS considered making the proposal to include diagnostic and therapeutic nuclear medicine services and supplies as a DHS effective immediately; however, CMS was persuaded that delaying the effective date until January 1, 2007 would be less disruptive to physicians who may choose to divest their investment and to beneficiaries who may need to receive services and supplies at another location.

O. Impact on Beneficiaries (p. 70328)

There are a number of changes made in this final rule with comment that would have an effect on beneficiaries. In general, CMS believes these changes will improve beneficiary access to services that are currently covered or will expand the Medicare benefit package to include new services. As explained in more detail below, the regulatory provisions may affect beneficiary liability in some cases.

P. Accounting Statements (pp. 70328-70335)

An accounting statement prepared by CMS provides the classification of the expenditures associated with the provisions of this proposed rule. The impact of proposed changes on providers/suppliers encompasses an anticipated negative update to the physician fee schedule based on the statutory SGR formula. Expenditures are classified as transfers to providers/suppliers receiving payment under the physician fee schedule or Medicare Part B.

Addendum A – Explanation and Use of Addendum B (pp. 70335-70336)

Addendum B – Relative Value Units and Related Information (pp. 70337-70463)

Addendum C – Codes with Interim RVUs (pp. 70463-70466)

Addendum D – 2006 Geographic Practice Cost Indices (GPCI) by Medicare Carrier and Locality (pp. 70466-70467)

Carrier	Locality	Locality Name	2006 Work GPCI	2006 PE GPCI	2006 MP GPCI
00836	02	Seattle (King Cnty), WA	1.014	1.131	0.819
00836	99	Rest of Washington	1.000	0.978	0.819

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Addendum E –2006 Geographic Adjustment Factors (GAFs) (pp. 70468-70469)

Carrier	Locality	Locality Name	2006 GAF
00836	02	Seattle (King Cnty), WA	1.058
00836	99	Rest of Washington	0.984

Addendum F – CAP: Revised Single Drug Category List (pp. 70469-70471)

Addendum G – CAP: Revised New Drugs for CAP Bidding for 2006 (p. 70471)

Addendum H - List of CPT/HCPCS codes used to describe nuclear medicine designated health services under section 1877 of the Social Security Act (pp. 70472-70476)